REMARKS

Claims 1-4, 8, 9, 15-18, 36, 37 and 40-46 are pending in the subject application and claims 40-45 are withdrawn from consideration. Claim 1 has been amended. Support for this amendment may be found *inter alia* in the specification of priority application 08/592,070 ('070 application) at page 29, line 18 to page 30, line 10. Applicants maintain that the amendment of claim 1 raises no issue of new matter and is fully supported by the specification. Applicants respectfully request that this Amendment be entered. Upon entry of this Amendment, claims 1-4, 8, 9, 15-18, 36, 37 and 46 will still be pending and under examination.

Claim of Priority

The Examiner asserts that the subject matter defined in claims 1-4, 8, 9, 15-18, 36, 37 and 46 has an effective filing date of August 5, 1997, which is the filing date of the subject application. The 08/592,070 application ("'070 application"), filed on January 26, 1996, allegedly fails to provide adequate support under 35 U.S.C. §112 for the instantly claimed invention.

Applicants respectfully traverse the Examiner's position regarding applicants' claim of priority with respect to claims 1-4, 8, 9, 15-18, 36, 37 and 46.

Claims 1-4, 8, 9, 15-18, 36, 37 and 46, as amended, provide a method of inhibiting atherosclerosis in a subject suffering from hyperlipidemia which comprises administering to the subject a polypeptide comprising the amino acid sequence of soluble receptor

for advanced glycation endproduct (sRAGE) or a derivative thereof capable of inhibiting an interaction between amyloid-β peptide and receptor for advanced glycation endproduct (RAGE) in an amount effective to inhibit atherosclerosis in the subject.

The test for enablement under 35 U.S.C. §112, first paragraph, is whether the disclosure contains sufficient information regarding the subject matter of the claims to enable one skilled in the relevant art to practice the claimed invention without undue experimentation.

The Examiner, on page 3 of the Office Action, concedes that the '070 application discloses a method for treating a subject with hyperlipidemic atherosclerosis by administering an agent capable of inhibiting the interaction of amyloid-β peptide with RAGE. The Examiner, also on page 3, further concedes that the '070 application discloses the use of sRAGE as the agent in the method. However, the Examiner asserts that the specification does not demonstrate that the interaction of amyloid-β peptide with RAGE is actively involved in hyperlipidemic atherosclerosis, disclose that administration of sRAGE will treat hyperlipidemic atherosclerosis, or provide adequate guidance or working examples that teach an artisan how to practice a method to treat hyperlipidemic atherosclerosis by administering sRAGE. The Examiner further asserts that there was no sufficient teaching in the art regarding the treatment of hyperlipidemic atherosclerosis with sRAGE at the time the '070 application was filed.

In response, applicants respectfully point out that according to section 2164.02 of the M.P.E.P., "[t]he specification need not

contain an example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation." As a result, applicants maintain that working examples that teach an artisan how to practice a method to inhibit atherosclerosis in a subject suffering from hyperlipidemia by administering sRAGE is unnecessary.

Furthermore, according to section 2164.05 of the M.P.E.P., applicant may demonstrate that the disclosure, as filed, would have enabled the claimed invention for one skilled in the art at the time of filing by providing a declaration after the filing date which demonstrates that the claimed invention works. Applicants have, in fact, so demonstrated this, as evidenced by the filing of the subject application. This application clearly demonstrates that administration of sRAGE inhibits atherosclerosis in a subject suffering from hyperlipidemia.

Accordingly, applicants maintain that the '070 Application provides adequate support under 35 U.S.C. §112 for the subject matter of claims 1-4, 8, 9, 15-18, 36, 37 and 46, as amended. As a result, the subject matter of claims 1-4, 8, 9, 15-18, 36, 37 and 46, is entitled to an effective filing date of January 26, 1996, which is the filing date of the '070 application.

Rejection under 35 U.S.C. §112, Second Paragraph

The Examiner rejected claims 1-4, 8, 9, 15-18, 36, 37 and 46 under 35 U.S.C. §112, second paragraph, as allegedly indefinite. Specifically, the Examiner asserted that the phrase "the

extracellular domain of soluble receptor for advanced glycation endproduct (sRAGE)" in claim 1 is confusing.

In response to the Examiner's rejection, but without conceding the correctness thereof, applicants point out that amended claim 1 no longer recites "the extracellular domain of soluble receptor for advanced glycation endproduct (sRAGE)."

In addition, the Examiner asserted that because there is no sequence identifier provided for the specific extracellular domain recited in claim 1, it is unclear which extracellular domain (sRAGE) or which RAGE is referred to in claim 1.

In response, applicants respectfully traverse this rejection. Applicants maintain that there is no confusion as to which sRAGE is referred to in claim 1 because the amino acid sequence of sRAGE is disclosed in the '070 application on page 29, line 18 to page 30, line 10. As a result, no sequence identifier is required for claim 1.

In view of the above remarks, applicants maintain that claims 1-4, 8, 9, 15-18, 36, 37 and 46 satisfy the requirements of 35 U.S.C. §112, second paragraph.

Rejection Under 35 U.S.C. §102(e)

The Examiner rejected claims 1-4, 8, 9, 15-18, 36, 37 and 46 under 35 U.S.C. 102(e) as allegedly anticipated by U.S. Patent No. 5,864,018 ("Morser").

In response, applicants respectfully traverse this rejection.

A rejection based on 35 U.S.C. §102(e) can be overcome by perfecting priority under 35 U.S.C. §120 by amending the specification of the application to contain a specific reference to a prior application. Applicants contend that the claimed invention is entitled to a priority date of January 26, 1996 as discussed above. Therefore, since Morser is only available as a reference as of August 16, 1996, i.e. after the January 26, 1996 effective filing date of the claimed invention, Morser is not available as a §102(e) reference.

In view of the above remarks, applicants maintain that claims 1-4, 8, 9, 15-18, 36, 37 and 46 satisfy the requirements of 35 U.S.C. §102(e).

Summary

For the reasons set forth hereinabove, applicants respectfully request that all the claims of this application be allowed, and that the application proceed to issuance.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop AF; Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

2/12/07

Alan J. Morrison
Reg. No. 37,399

Date

John P. White
Registration No. 28,678
Alan J. Morrison
Registration No. 37,399
Attorneys for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
Tel. No. (212) 278-0400